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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/698,047

10/30/2003

Douglas M. Zatezalo

VI/99-016.CIP.C

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07/14/2006

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EXAMINER

HORWAT, JENNIFER A

ART UNIT

PAPER NUMBER

3768

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/698,047 | ZATEZALO ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer Horwat | 3768 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The double patenting rejection on the grounds of nonstatutory obviousness-type double patenting over U.S. Patent No. 6643537 (the '537 patent) in view of Cain (US 5984368) has been overcome by the terminal disclaimer submitted by applicant. It is noted, however, that a double patenting rejection was not made over Cain and therefore there is no separate rejection to be withdrawn. The Cain reference was merely used to modify the '537 patent in support of the obviousness-type double patenting rejection that was made.

Response to Arguments

Applicant argues that the Engelson reference does not teach or suggest the use of a fluid system with two drive mechanisms and two illumination devices, wherein the first illumination device emits a first color and the second illumination device emits a second color. However, examiner respectfully disagrees. As seen in figure 2, for each bedside, and therefore each patient, a multitude of pumps, or drive mechanisms, are included. Each pump is connected to the bedside display which includes the screen as shown in figures 7, 8, and 9. As shown in figure 7, each drug has a separate illumination device which displays the status of each injection system, including the substance being administered and any alarms. Further, Engelson discloses that the video display may be color coded to indicate the status and schedule of each drug administration (figure 9). This implies that different colors are used.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a dual syringe, specific motor configurations, and advantages of the system over the prior art) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 15-17, 19-26, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Engleson, et al (US 6671563). Engleson discloses a fluid injection system in which multiple fluid containers are connected to pumps, which serves as the drive mechanism, in order to deliver various fluids to patients (figure 2). Each fluid container is operably associated with a drive mechanism, which are controlled by the bedside CPU, or controller (figure 2). The system includes visual displays and touch screens (col 5, lines 15-16) for interfacing with the system and to allow for monitoring the infusion pump by providing status information of the pump on the display (col 10).

The illumination device is interpreted to be the bedside display, each with a plurality of elements, including graphics and text, which allow information to be communicated to the medical professional. The programmed infusion regimen may be adjusted using the touch screen after evaluating the status of the infusion that is displayed on the video display (col 10 and figure 11). The display includes graphical, lexical, and numerical which may be color-coded to indicate the status and schedule of each drug administration for each patient (col 9). An alarm condition is displayed on the video display, which flashes red to "attract attention to the alert" (col 10).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson in view of Uber, III et al (US 5494036). Engleson, as discussed above, uses a pump as an infusion system and does not disclose the use of a syringe having a plunger and a piston adapted to engage the plunger of the syringe. Uber discloses a contrast infusion system in which two motors are used to engage the plungers (figure 1, elements 40 and 42) of two syringes inside the injector unit (figure 1, element 38). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Engleson with the disclosure of Uber and use a syringe system

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in place of the pump infusion system, as a syringe allows precisely controlled and measured injection of contrast, medication, or other fluid to a patient.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson in view of Niehoff (US 5681286). Engleson, as discussed above, discloses using a flashing icon to alert a problem with the infusion pump as well as using various icons, graphics, and text to monitor the status of the infusion pump. However, Engleson fails to disclose explicitly using either a flashing, on, or off condition to signify the state of the system. Niehoff teaches the use of an LED as an indicator for an infusion system in which the LED flashes when the plunger is moving, is steady when the system is locked, and would be off when the system is off. Based on this teaching, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system disclosed by Engleson to use a flashing condition, a steady condition, and a off condition to signify the status of the injection system.

6. Claims 27, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson in view of Cain (US 5984368). Engleson, as discussed above, substantially discloses the invention as claimed. However, Engleson does not disclose using the same color-coding used on the graphical display on the fluid containers themselves. However, Cain teaches that it is known in the art to match medications from a time chart to the medicine containers as well (col 2, lines 25-29) and further that such charts may be "implemented as screen displays in a computer program" (col 9, lines 34-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to extend the color-coding already disclosed by Engleson

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to the fluid containers themselves in light of the teachings of the reference by Cain to reduce the chance of confusing the fluid containers.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

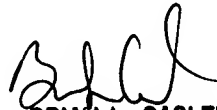
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-Th 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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7/7/06


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